REMARKS

Claims 1-62 are pending in the above-identified application and have been subjected to restriction by the Office Action under 35 U.S.C. §121 as follows:

I. Claims 1-11, 18-36, 50, 52 and 57-58, drawn to methods of preparing a solid drug dosage form that do not contain a lubricant, classified in class 424, subclass 464.

II. Claims 12-17, 51, drawn to methods of preparing a solid drug dosage form that contain a lubricant, classified in class 424, subclass 464.

III. Claims 38-48, 53-56 and 59-62, drawn to compositions, classified in class 424, subclass 464.

IV. Claim 49, drawn to a method of treating a disease in a patient requiring a sustained release formulation, classified in class 424, subclass 464.

It should be noted that at the outset, the Office Action has mischaracterized the subject matter of Group I. Although Group I may not list a lubricant as a necessary element in the dry formulation, this does not mean that the subject matter of Group I excludes a lubricant. It is to be noted that Claims 1 and 12 and claims dependent therein utilize the term comprising, which means that there are additional steps and components that may be utilized in preparing the pharmaceutical composition. There is no language in the claims of Group I that precludes the presence of a lubricant.

In order to be responsive to the Office Action, applicant elects, with traverse, the subject matter of Group III, i.e., claims 38-48, 53-56 and 59-62 for continued examination herein. Pursuant to the species requirement, applicant elects, with traverse, silicified microcrystalline cellulose as the cellulose species. In addition, applicant elects the mixture of hydroxypropylmethylcellulose and xanthan gum as the sustained release carrier and metformin as the drug.

In order to comply with the restriction requirement, applicant is also required to identify the claims corresponding to the elected invention. The claims that correspond to Group III are Claims 38-48, 53-56 and 59-62. The listing of claims that read on the elected species are Claims 38, 40, 41, 42, 43, 44, 45, 46, 47, 48, 54, 55, 56, 59 and 60.

Notwithstanding the foregoing, applicants hereby traverse, pursuant to 37 C.F.R. §§1.111 and 1.143, the requirement for restriction and request reconsideration thereof in view of the following remarks.

Applicant respectfully requests that the Restriction Requirement be withdrawn since it is not in compliance with 35 U.S.C. §121 and 37 C.F.R. §§1.141 and 1.142.

35 U.S.C. §121 provides that the Commissioner may restrict an application when two or more independent and distinct inventions are claimed in a single application (emphasis added). Similarly, 37 C.F.R. §1.141(a) permits restriction on condition that independent and distinct inventions are found within one application. Only the statutory requirement that the various groups of claims are "distinct" has been proferred as a basis for requiring the restriction. Even assuming, pro arguendo, that the Office Action was correct with respect to distinctiveness, there is absolutely no indication in the Office Action that Groups I-IV are also independent. In fact, applicants submit that there is an interdependence between each of the groups alleged to be patentably distinct.

MPEP §802.01 defines independent as follows:

> The term "independent" (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is they are unconnected in design, operation or effect...

Applicant respectfully submits that the subject matter in Groups I - IV are connected in design, operation or effect and are thus not dependent.

The subject matter of Group I is directed to a method of preparing an oral sustained release pharmaceutical composition comprising a solid drug dosage form that may contain, inter alia, a lubricant, while Group II is directed to the method for preparing an oral sustained release pharmaceutical composition which specifically recites the presence of a lubricant, Group III is directed to the product prepared by the process recited in Group I or II, and Group IV is directed to the use of the product in Group III prepared from the process of Group I or II. Thus, Groups I-IV are related and are not independent. Consequently, because the Office Action has not even alleged the statutory required "independence" of these groups and further because these groups of claims are connected in design, operation and/or effect and are therefore not independent, the claims which the Office Action has grouped separately are not "independent and distinct" so as to justify the Restriction Requirement. It is therefore respectfully submitted that the Restriction Requirement is improper and cannot be maintained.

It is respectfully submitted, that in the least, Groups I and II should be considered as one invention. As indicated hereinabove, Group I does not list a lubricant as an element. But, there is no language in the claims of Group I that precludes the presence of a lubricant. Moreover, in Claim 1, the term "comprise" is utilized which means that it is open ended. Furthermore, the claims in Group I (as well as in Group II) are Jepson claims and the emphasis therefore is in the improvement. Thus, it can easily be seen that the subject matter in Group I is generic to the subject matter in Group II.

Moreover, it is noted that the classification system for all four Groups is class 424, subclass 464. Contrary to the allegations in the Office Action, there is no search and examination burden on the USPTO to examine all of the claimed subject matter since the different groups as defined by the Office Action are in the same classification. The USPTO need only conduct one search to find the applicable prior art. It is respectfully submitted that each of

the groups do not have a separate status in the art and that the field of search for each of the groups is the same. Inasmuch as there is no clear indication of separate future classification and field of search, in accordance with MPEP § 808.02, no reason exists for dividing among those related groups. Thus, for a second reason, this restriction requirement is improper and should be withdrawn.

Further, with respect to the species requirement, the Office Action makes mere allegations and conclusions without providing any rationale. It did not show that the species are independent and distinct. In fact, the species requirement did not make any allegations of independence or distinctiveness. Thus, inasmuch as the species requirement makes mere conclusions with respect to the species requirement, the USPTO has not met its burden. Consequently, the species requirement does not comply with 35 U.S.C. §121 or 37 C.F.R. §1.141.

This species requirement is also not in compliance with MPEP §808. MPEP §808 states:

> Every requirement to restrict has two aspects: (a) the reasons (as distinguished from the mere statement of conclusion) why the invention as claimed are either independent or distinct and (b) the reasons for insisting upon restriction therebetween.

The Office Action, merely concludes that the species are patentably distinct. It did not provide any reasons why the species are patentably distinct. In addition, it has not provided any reasons for insisting upon restriction therebetween.

Thus, the Office Action has not complied with the statute, regulations or the MPEP. Therefore, it is also improper for the Office Action to restrict the subject matter to the elected group and the elected species.

It is vital to all applicants that the restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications, which are filed, to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. § 121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that 35 U.S.C. § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle mbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 228 U.S.P.Q. 837, 840 (Fed. Cir. 1986); and in Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q 2d 1436 (Fed. Cir. 1990), that court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public's interest in the legitimacy of issued patents, applicant respectfully urges the Examiner not to require restriction in cases such as the present application wherein various aspects of a unitary invention are claimed.

In addition, the Courts have recognized the advantages to the public interest to permit the patentee to claim all aspects of their invention, as the applicant has done herein, so as

to encourage the patentee to make a more detailed disclosure of all aspects of his invention. The CCPA has observed:

> We believe that the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. § 112 all aspects of what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456, F.2d 658, 666, 177 U.S.P.Q. 250 (CCPA 1973).

Furthermore, applicant respectfully requests that in view of increased Official Fees and the potential limitation of applicant's financial resources, +contravenes the constitutional intent to promote and encourage the progress of science and the useful arts.

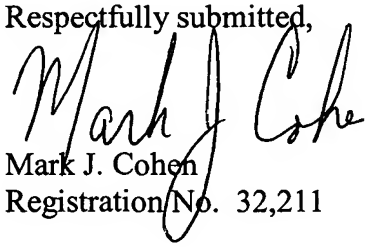
Hence, it is respectfully requested that the Examiner reconsider and withdraw the Restriction Requirement, and provide an action on the merits with respect to all of the claims and the full scope of the subject matter being claimed.

Applicant has amended Claims 40 and 56 to correct typographical errors therein, and has amended Claim 43 to provide antecedent basis for the term "cellulose" recited therein.

No new matter is added to the application.

Wherefore, the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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